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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,873

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Javier Ara Pinilla

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EXAMINER

CUMBERLEDGE, JERRY

ART UNIT

PAPER NUMBER

3733

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,873	<b>Applicant(s)</b> ARA PINILLA ET AL.	
	<b>Examiner</b> JERRY CUMBERLEDGE	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 6-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 8 is objected to because of the following informalities:

In claim 8 there exists an inconsistency, thus making the scope of the claim unclear. In the claim 8, lines 2-3 applicant recites “a template” with the template being only functionally recited, i.e. “...for the attachment of a template for drilling into the bone...”, thus indicating that the claim is directed to the subcombination, “an intramedullary nail assembly”. However, in lines 3-4, applicant positively recites the template as part of the invention, i.e. “...a template for drilling into the bone, which is situated in line with the holes of the support...”, thus indicating that the combination, the intramedullary nail assembly and the template, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 8 will be considered as being drawn to the subcombination, the intramedullary nail assembly.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "its distal end" in 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "its proximal end" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the proximal end" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the threaded rod" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is recited as being dependent on cancelled claim 5. Claim 9 will be considered to be dependent on claim 6 for examination purposes. Correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 7 and 8 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 7, lines 3, applicant positively recites part of a human, i.e. "that is fixed by screws to the bone". Thus claims 7 and 8 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Santangelo (US Pat. 5,534,004).

Santangelo discloses an intramedullary nail (Fig. 3) which is specially designed to secure and immobilize fractures in long bones having a medullary cavity of a given length such as the femur (Fig. 3), said nail consisting of the functional combination of a tubular nail (Fig. 3, ref. 5) and a probe (Fig. 3, internal mechanism comprising refs. 20, 11, 9) that can move axially inside of said tubular nail (Fig. 4), which includes a node (Fig. 3, ref. 16) and a plurality of thin rods (Fig. 3, ref. 15) of a length less than said given length (Fig. 3) extending distally (Fig. 3), which are grouped according to an imaginary cylindrical surface (Fig. 3)(Fig. 4) and converge towards the node (Fig. 3), beyond which they extend in wide sections that are independent at their free ends (Fig. 3), whilst the probe includes a protrusion close to its distal end (Fig. 3, ref. 14, including

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ref. 19), which is initially situated outside the tubular nail (Fig. 3)(Fig. 4, at least partially), characterized in that the tubular nail further includes a head at its proximal end (Fig. 3, near ref. 5a), from which the plurality of thin rods extend distally (Fig. 3)(Fig. 4) and the protrusion first causes the radial deformation of the wide sections of the rods during the axial movement of the probe relative to the tubular nail (Fig. 3, ref. 19 abutting the rods, forcing them outward) and then causes the node to move towards the head (Fig. 3, by engagement of ref. 14 with the end of the device), which in turn causes a radial expansion of the tubular nail in the proximal area at its rods (Fig. 3, as refs. 9 extends. An assembly for use in a bone having spongy tissue lining its medullary cavity (Fig. 4), characterised in that said independent free ends of said wide sections of said thin rods are adapted to almost reach a perpendicular position relative the bone (Fig. 3, as they may be bent that far, if one so desires), to be driven into the spongy tissue lining the medullary cavity (Fig. 3).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Santangelo, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not

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differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santangelo (US Pat. 5,534,004) in view of Aginsky (US Pat. 4,227,518).

Santangelo discloses the claimed invention except for the assembly comprises a support with a stepped axial hole and a radial fin with a pair of holes for screwing the support to the bone. The axial hole has a threaded section.

Aginsky discloses an intramedullary nail assembly (Fig. 1) that comprises a support (Fig. 1, refs. 15, 16) with a stepped axial hole (Fig. 2, hole through refs. 16 and 15) and a radial fin (Fig. 1, ref. 18)(Fig. 5, ref. 18) with holes (Fig. 5, ref. 32). The axial hole has a threaded section (Fig. 2, threaded portion of ref. 16). This mechanism is useful for preventing rotation (column 4, lines 6-21).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the assembly of Santangelo with a support

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system as taught by Aginsky, in order to help prevent rotation of the assembly (column 4, lines 6-21).

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-1346. The examiner can normally be reached on Monday-Friday 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733